

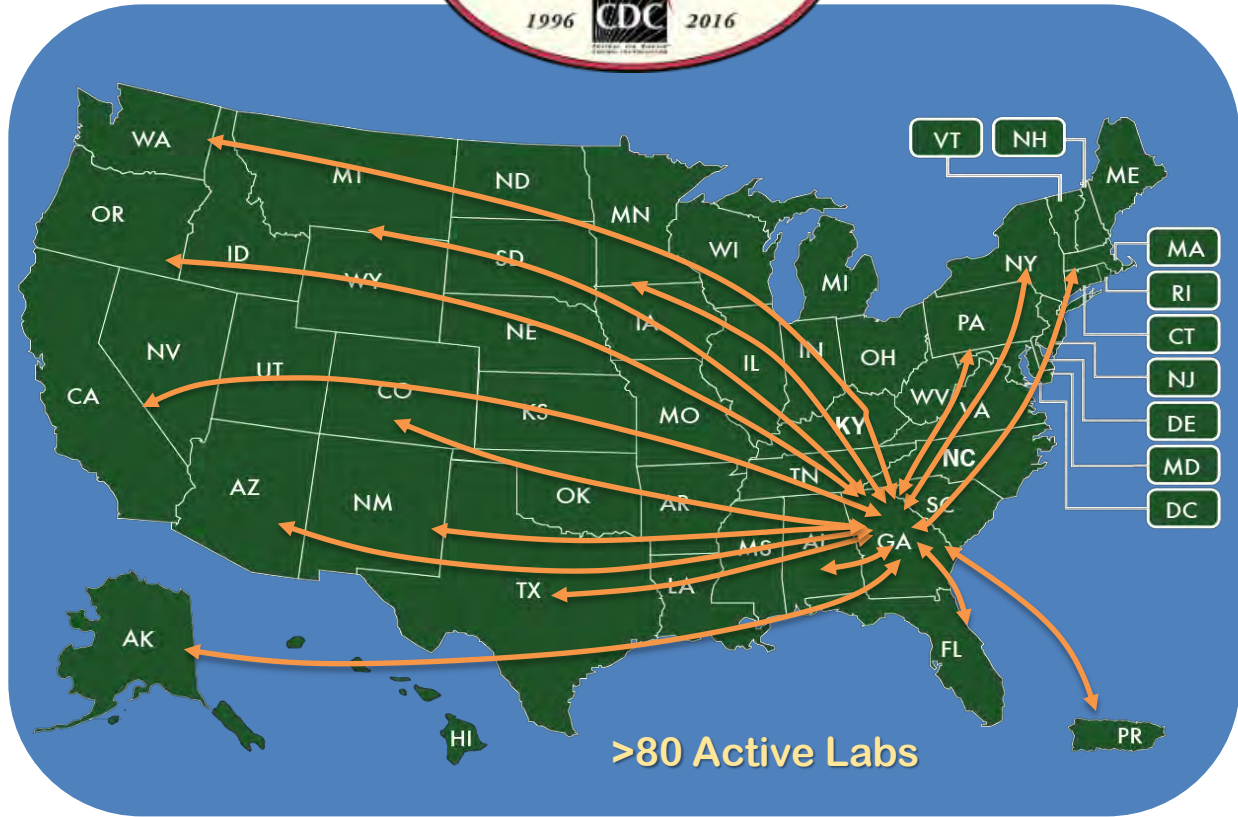
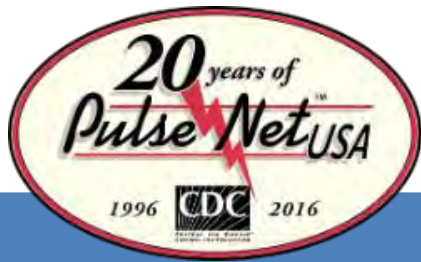
Surveillance of Foodborne Pathogens

Peter Gerner-Smidt, MD, DSc
Branch Chief

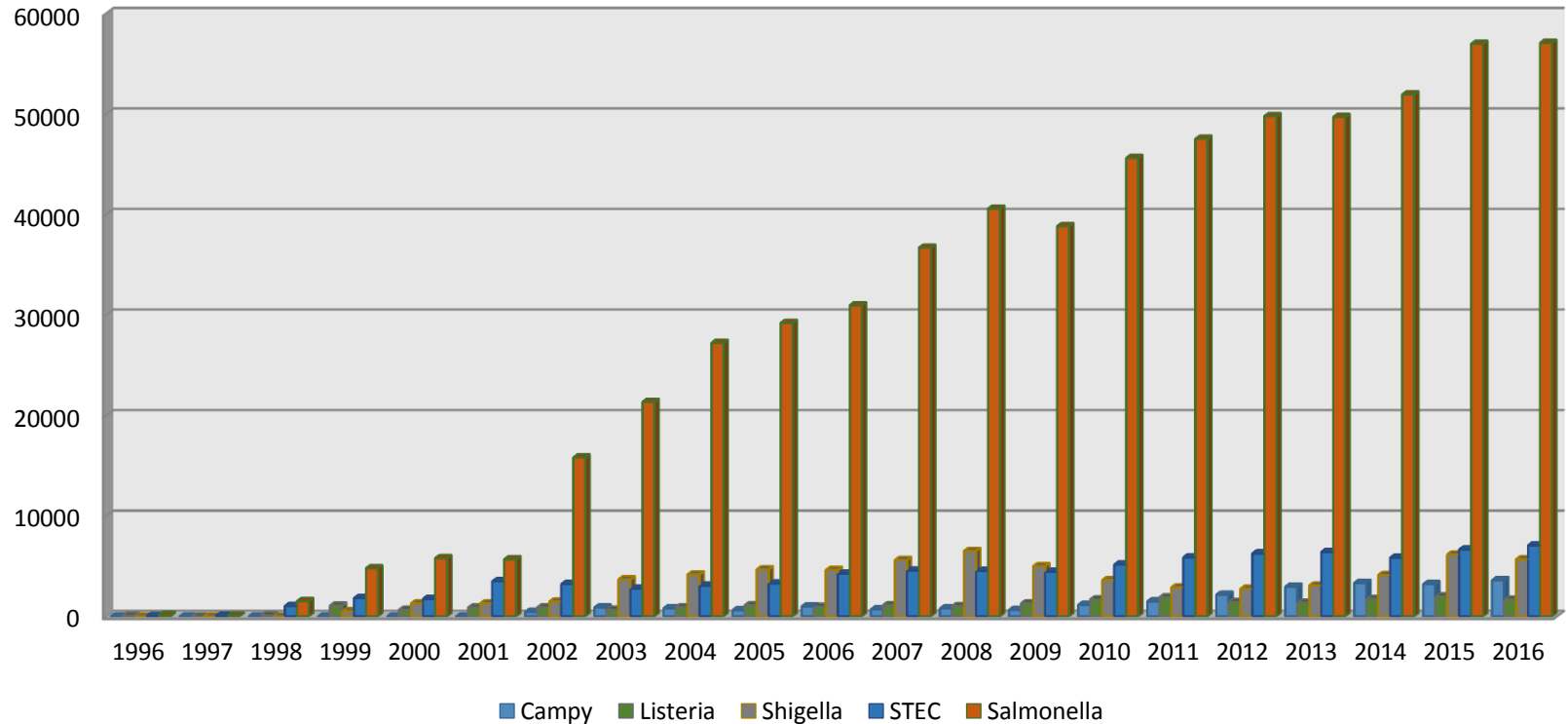


Food Safety Summit 2017

Session 16: When FDA Comes Knocking: How the Pathogens in Your Drain Could Lead to Criminal Charges

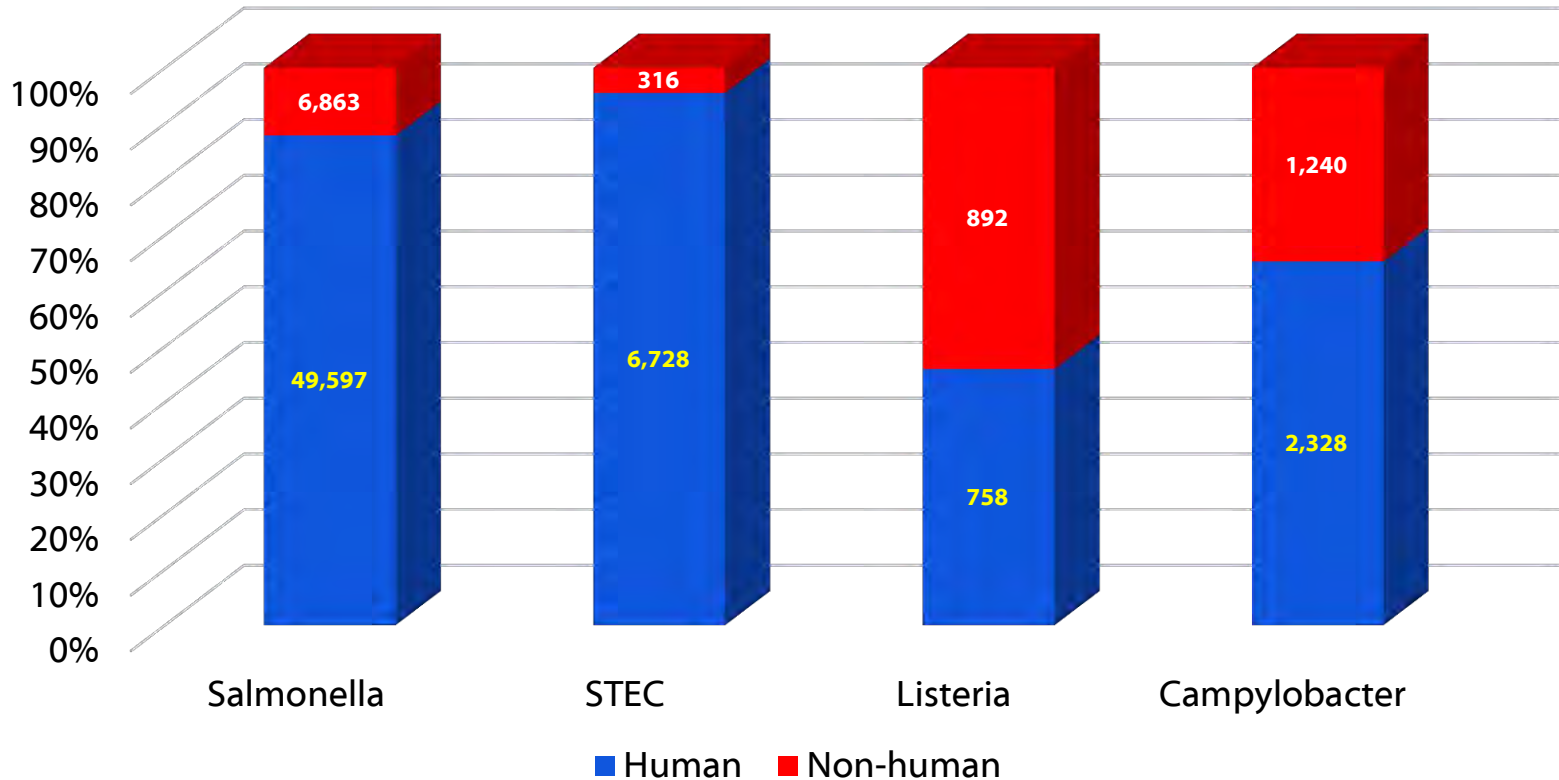


PulseNet Isolates, by Organism 1996-2016

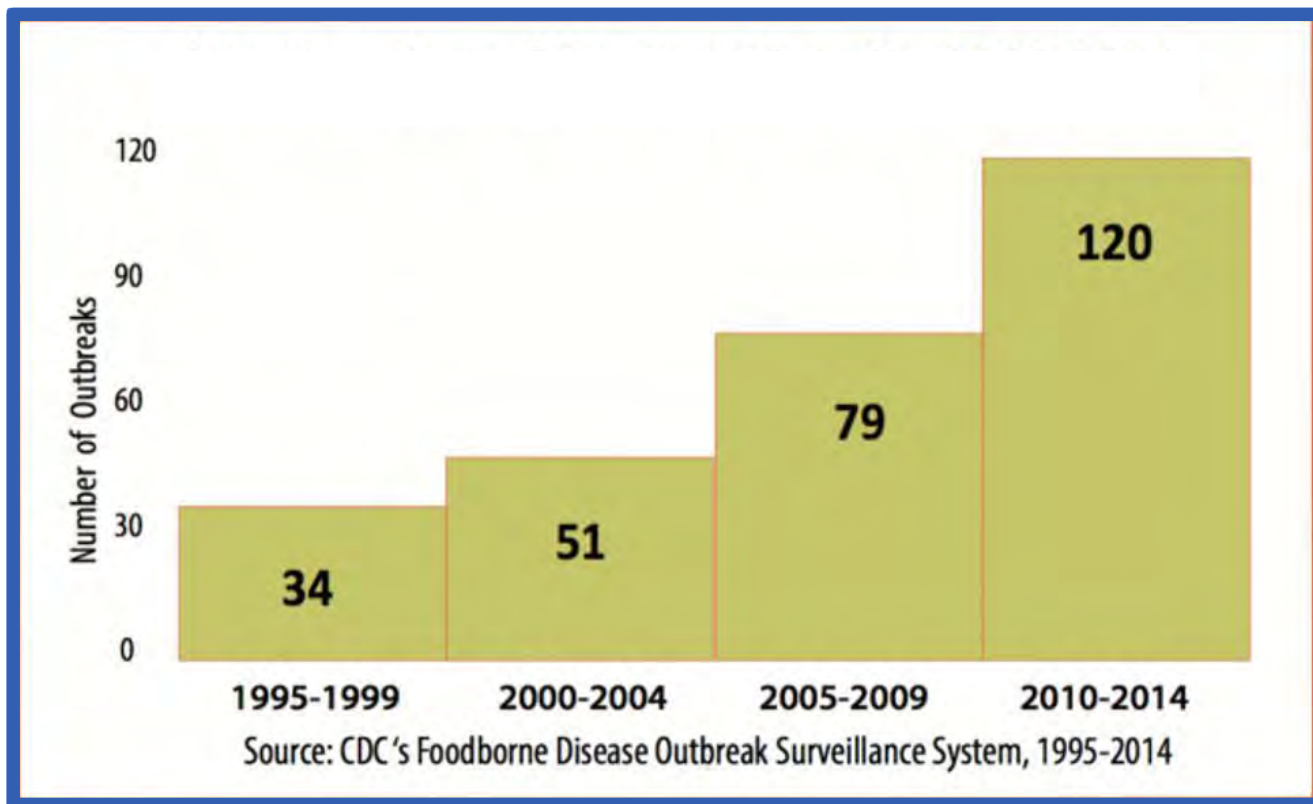


Uploads To PulseNet by Organism and Source 2016

Total **Human: 59,411**, **Non-human: 9,311**

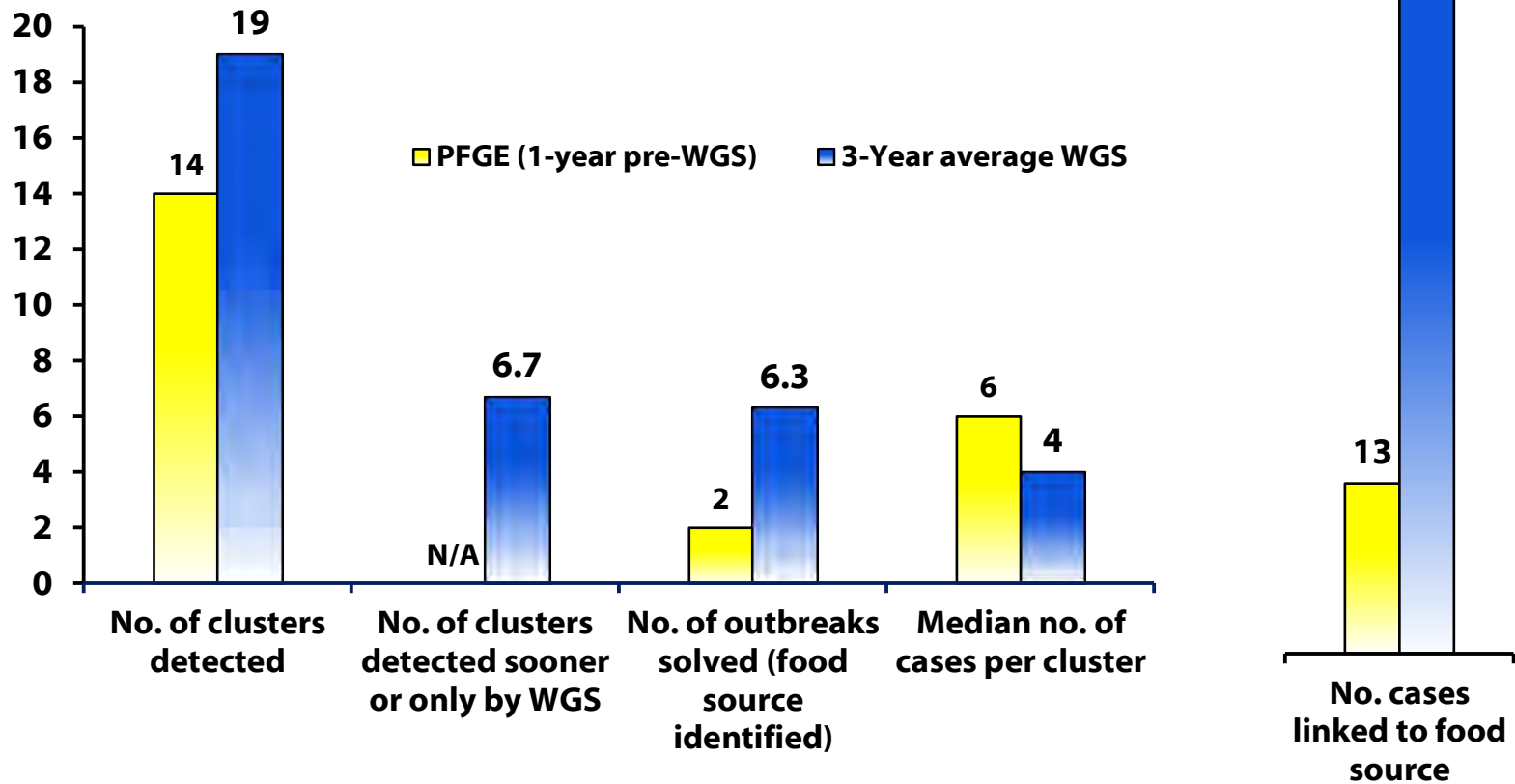


More Outbreaks Are Detected



Real-time WGS Improves Laboratory Surveillance

Listeria Metrics



Whole Genome Sequencing Capacity in PulseNet

- As of May 1, 2017
 - 36 laboratories in 33 states with capacity and trained
 - Public health laboratories in 49 states have or are in the process of procuring sequencers
- Goals:
 - Sequencers in all 50 states by the end of 2017
 - All trained by the end of 2018
 - WGS replace PFGE for real-time surveillance in the states by the beginning of 2019

The Dark Cloud Hanging Over Outbreak Surveillance: Culture-Independent Diagnostic Tests (CIDT)



CIDT



No
Cultures





ENVIRONMENTAL MONITORING TO VALIDATE SANITATION PREVENTIVE CONTROLS (*AND PREVENT FOODBORNE DISEASE OUTBREAKS*)

Hal King, Ph.D.
President/CEO

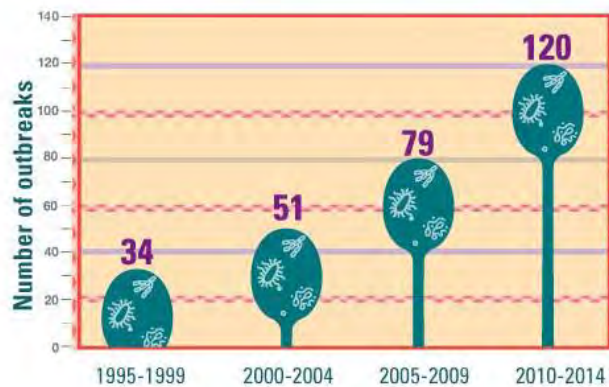
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MULTISTATE FOODBORNE DISEASE OUTBREAKS CONTINUE TO INCREASE IN THE UNITED STATES

More multistate outbreaks are being found

Why? Better methods to detect and investigate, and wider food distribution.



SOURCES: CDC National Outbreak Reporting System, 1995-2014,
Source: CDC Vital Signs MMWR, November 2015.

Multistate outbreaks: less common, but more serious

Why? The deadly germs *Salmonella*, *E. coli* and *Listeria* cause **91%** of multistate outbreaks.

Only 3%
of all US foodborne outbreaks are multistate, but they cause more than their share of outbreak sicknesses, hospitalizations and deaths:



Vital^{CDC}signs™

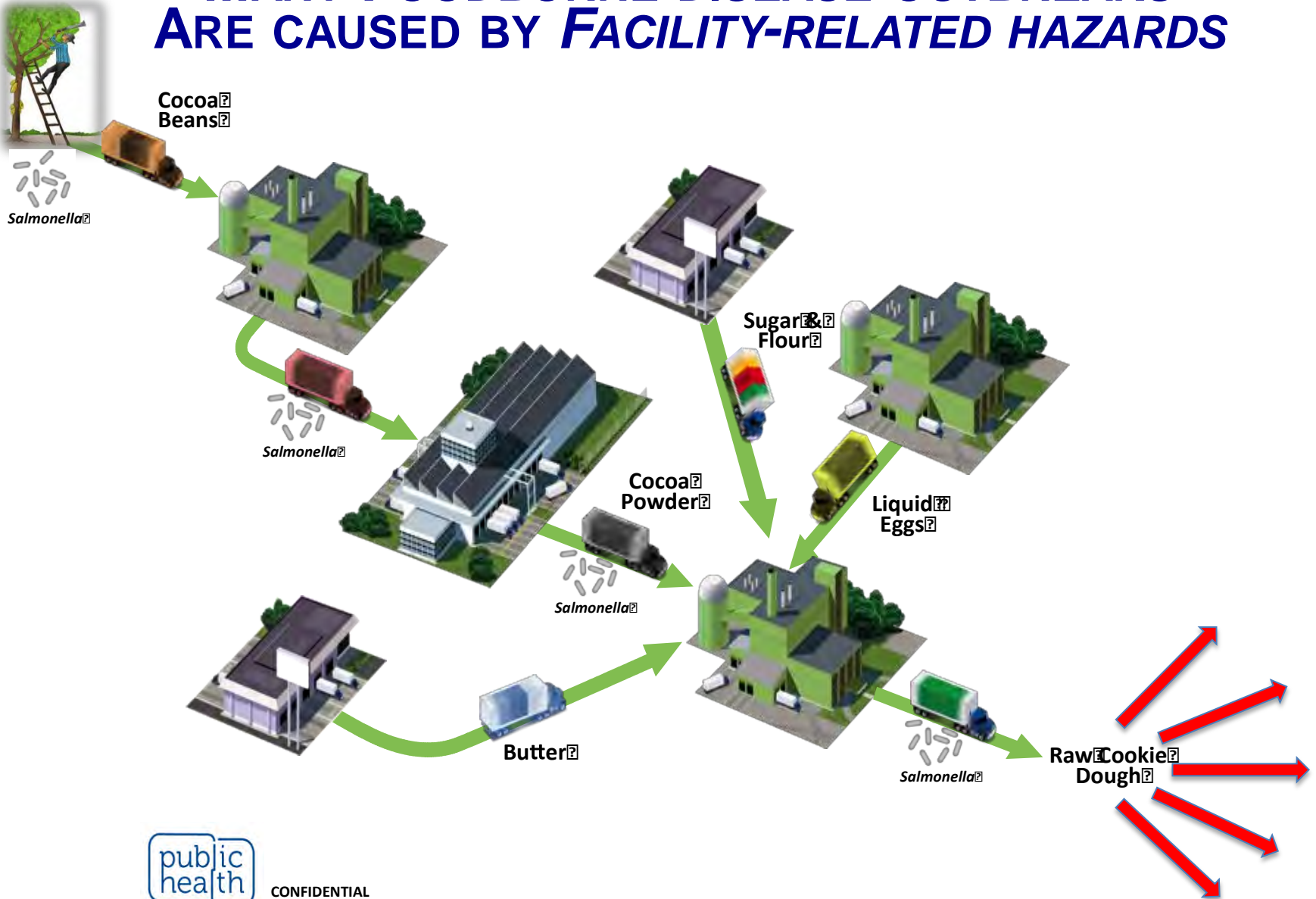
www.cdc.gov/vitalsigns/foodsafety-2015



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MANY FOODBORNE DISEASE OUTBREAKS ARE CAUSED BY *FACILITY-RELATED HAZARDS*



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MANY FOODBORNE DISEASE OUTBREAKS ARE CAUSED BY *FACILITY-RELATED HAZARDS*

Source of Hazards

Transient Pathogens	Resident (Persistent) Pathogens
<ul style="list-style-type: none">• Normally come into a food processing facility via raw ingredients, packaging, personnel, pests, and outside environments (leaking roofs)• When associated with ingredients (potential hazards), product processing stream and environment is expected to sometimes test positive• Normally removed and eliminated via cleaning and sanitation, pest control, facilities maintenance, personal hygiene• Typically do not become established in the food processing environment	<ul style="list-style-type: none">• Transient pathogens that become established and persist/survive in the environment• Can persist for long periods of time and may provide source (biofilms) of additional strains of resident pathogens when left undisturbed• Normally species (e.g., <i>Listeria monocytogenes</i>) specific but can include groups of strains of a species that change over time• Normal cleaning and sanitation may not eliminate• More likely to contaminate RTE foods during food processing

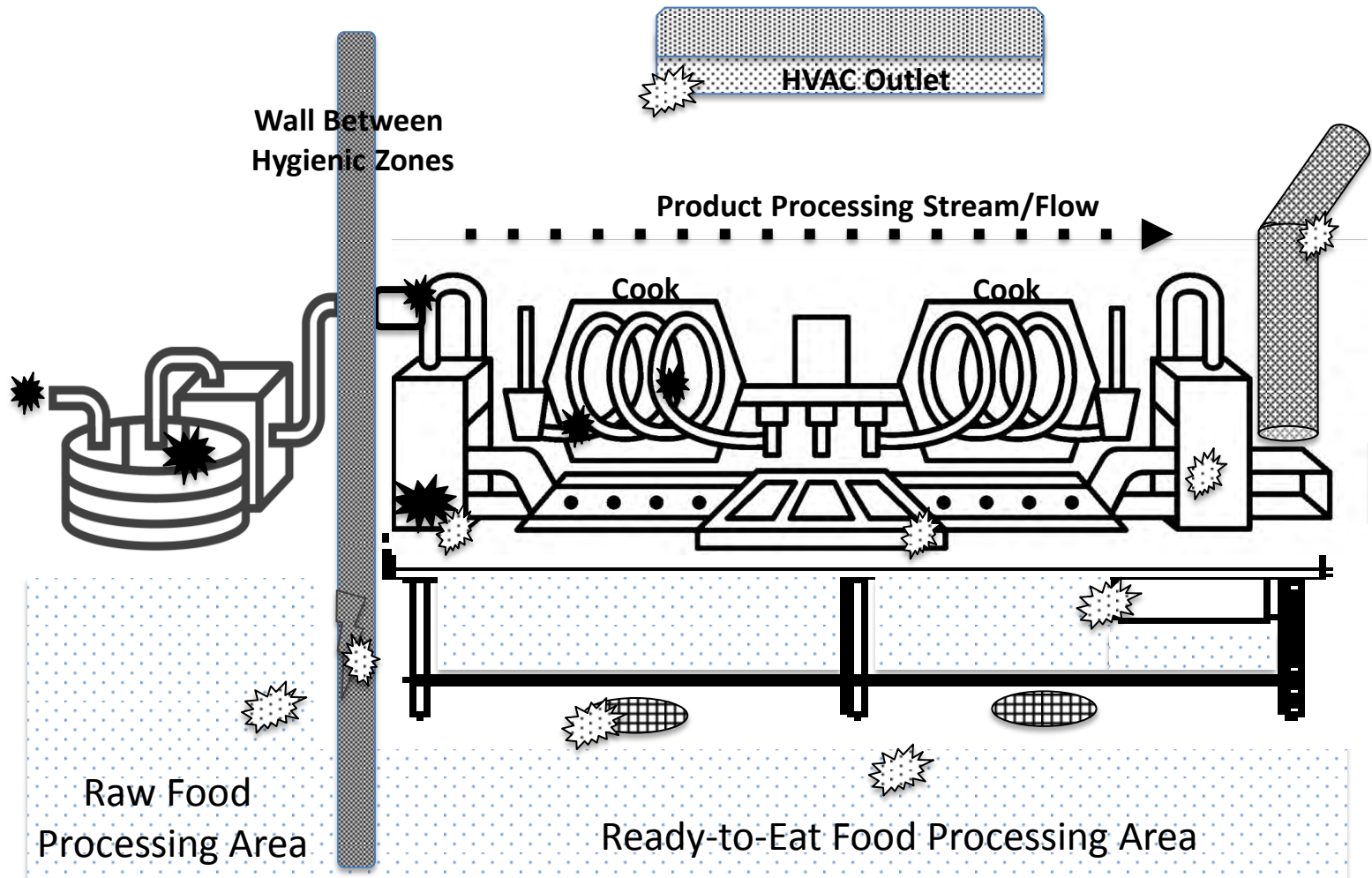
Source: Adapted from Food Safety Preventive Controls Alliance (2016)



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MANY FOODBORNE DISEASE OUTBREAKS ARE CAUSED BY *FACILITY-RELATED HAZARDS*



 **Transient Pathogens**
 **Resident/Persistent Pathogens**

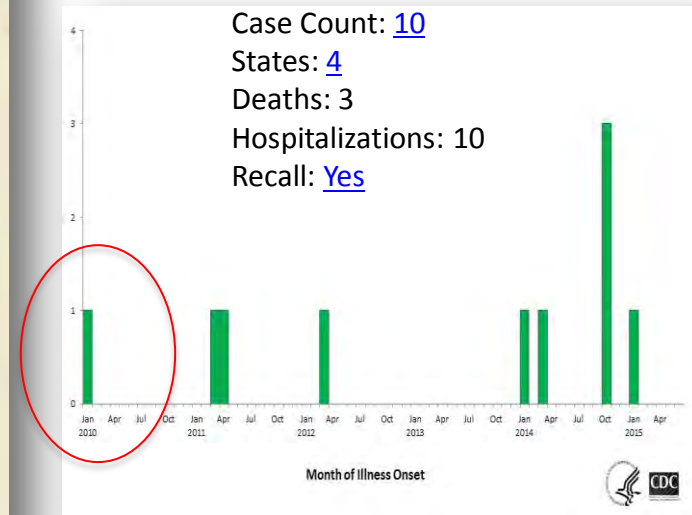
MANY FOODBORNE DISEASE OUTBREAKS ARE CAUSED BY FACILITY-RELATED HAZARDS

Multistate Outbreak of Listeriosis Linked to Blue Bell Creameries Products

For Example



At a Glance:



Source: Centers for Disease Control and Prevention (2015)



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MANY FOODBORNE DISEASE OUTBREAKS ARE CAUSED BY *FACILITY-RELATED HAZARDS*

Source of Hazards

Description of Category	Potential Sources of <i>Listeria monocytogenes</i>
Ingredients	<ul style="list-style-type: none"> • Raw foods, such as: <ul style="list-style-type: none"> ○ Raw meat, poultry, and seafood ○ Raw milk ○ Raw produce
Processing materials	<ul style="list-style-type: none"> • Compressed air • Ice • Brine solutions used in chilling refrigerated RTE foods
Contact surfaces for RTE foods	<ul style="list-style-type: none"> • Fibrous and porous-type conveyor belts • Filling and packaging equipment • Belts, peelers, and collators • Containers, bins, tubs and baskets • Slicers, dicers, shredders and blenders • Utensils • Gloves
Surfaces that generally do not contact RTE foods	<ul style="list-style-type: none"> • In-floor weighing equipment • Cracked hoses • Hollow rollers for conveyances • Equipment framework • Wet, rusting, or hollow framework • Open bearings within equipment • Poorly maintained compressed air filters • Condensate drip pans • Motor housings • Maintenance tools (e.g., wrenches and screwdrivers) • Forklifts, hand trucks, trolleys, and racks • On/off switches • Vacuum cleaners and floor scrubbers • Trash cans and other such ancillary items • Tools for cleaning equipment (e.g., brushes and scouring pads) • Spiral freezers/blast freezers • Ice makers • Aprons
Plant environment	<ul style="list-style-type: none"> • Floors, especially cracks and crevices • Walls • Drains • Ceilings, overhead structures, and catwalks • Wash areas (e.g., sinks), condensate, and standing water • Wet insulation in walls or around pipes and cooling units • Rubber seals around doors, especially in coolers • Metal joints, especially welds and bolts • Contents of vacuum cleaners

Source: Food and Drug Administration (2017)

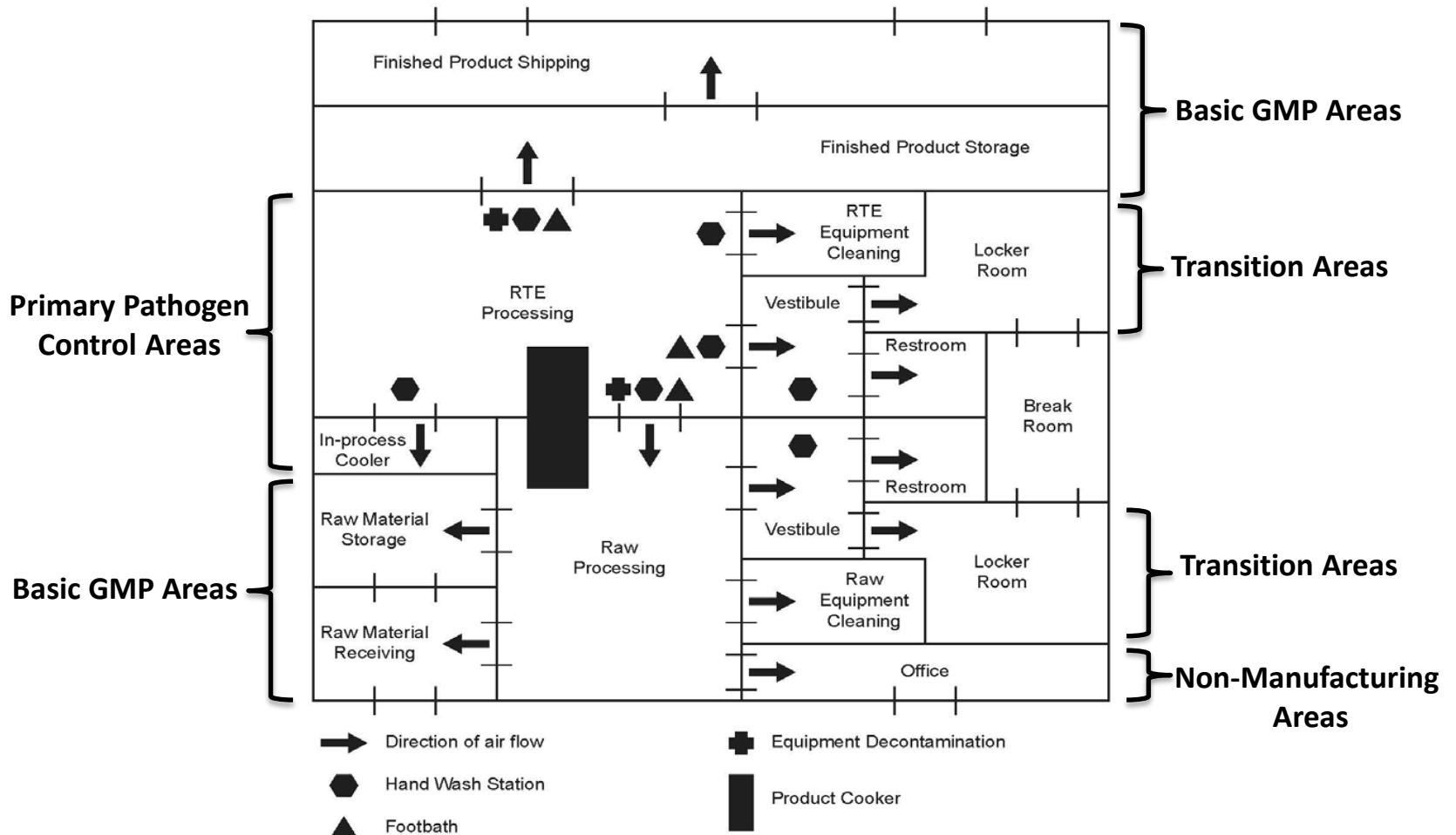


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FACILITY-RELATED HAZARDS CAN BE PREVENTED BY EFFECTIVE SANITATION PREVENTIVE CONTROLS

Hygienic Zoning: define processing areas and SOP's



Source: Adapted from Food and Drug Administration (2017)

FACILITY-RELATED HAZARDS CAN BE PREVENTED BY EFFECTIVE SANITATION PREVENTIVE CONTROLS

Testing locations: define where hazards most likely will occur

Zones	Description	Examples
Zone 1	Food-contact surfaces (FCS)	Utensils, table surfaces, slicers, pipe interiors, tank interiors, filler bowls, packaging and conveyors, hoppers.
Zone 2	Non-food-contact surfaces in close proximity to food and food contact surfaces.	Equipment housing or framework, and some walls, floors or drains in the immediate vicinity of FCSs carts
Zone 3	More remote non-food-contact surfaces that are in or near the processing areas and could lead to contamination of zones 1 and 2	Forklifts, hand trucks, and carts that move within the plant and some walls, floors or drains not in the immediate vicinity of FCSs
Zone 4	Non-food-contact surfaces, remote areas outside of the processing area, from which environmental pathogens can be introduced into the processing environment	Locker rooms, cafeterias, and hallways outside the production area or outside areas where raw materials or finished foods are stored or transported



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FACILITY-RELATED HAZARDS CAN BE PREVENTED BY EFFECTIVE SANITATION PREVENTIVE CONTROLS

Environmental monitoring for facility-related hazards

The FDA also recommends that the EMP following the following guidelines:

- Be written and documented
- Be scientifically valid
- Specify whether you are testing for *Listeria* spp. or *Listeria monocytogenes* (or *Salmonella* or *E. coli* if testing for these pathogens)
- Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites should be adequate to determine whether *Listeria* and other pathogen control measures are effective
- Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples should be adequate to determine whether *Listeria* and other pathogen control measures are effective
- Identify the test(s) conducted, including the analytical method(s) used to test for *Listeria* spp. or *Listeria monocytogenes* or other pathogens
- Identify the laboratory you are using for conducting the testing. Ensure the laboratory is accredited to perform pathogen testing and will prevent false positive and negative results by using proper aseptic methods and controls
- Specify corrective actions (consistent with the 2017 FDA guidance document) you will use when *Listeria* spp., *Listeria monocytogenes* or other pathogens are found
- Include allergen testing where appropriate using in-house sampling and testing or laboratory-assisted testing

Source: Adapted from Food and Drug Administration (2017)

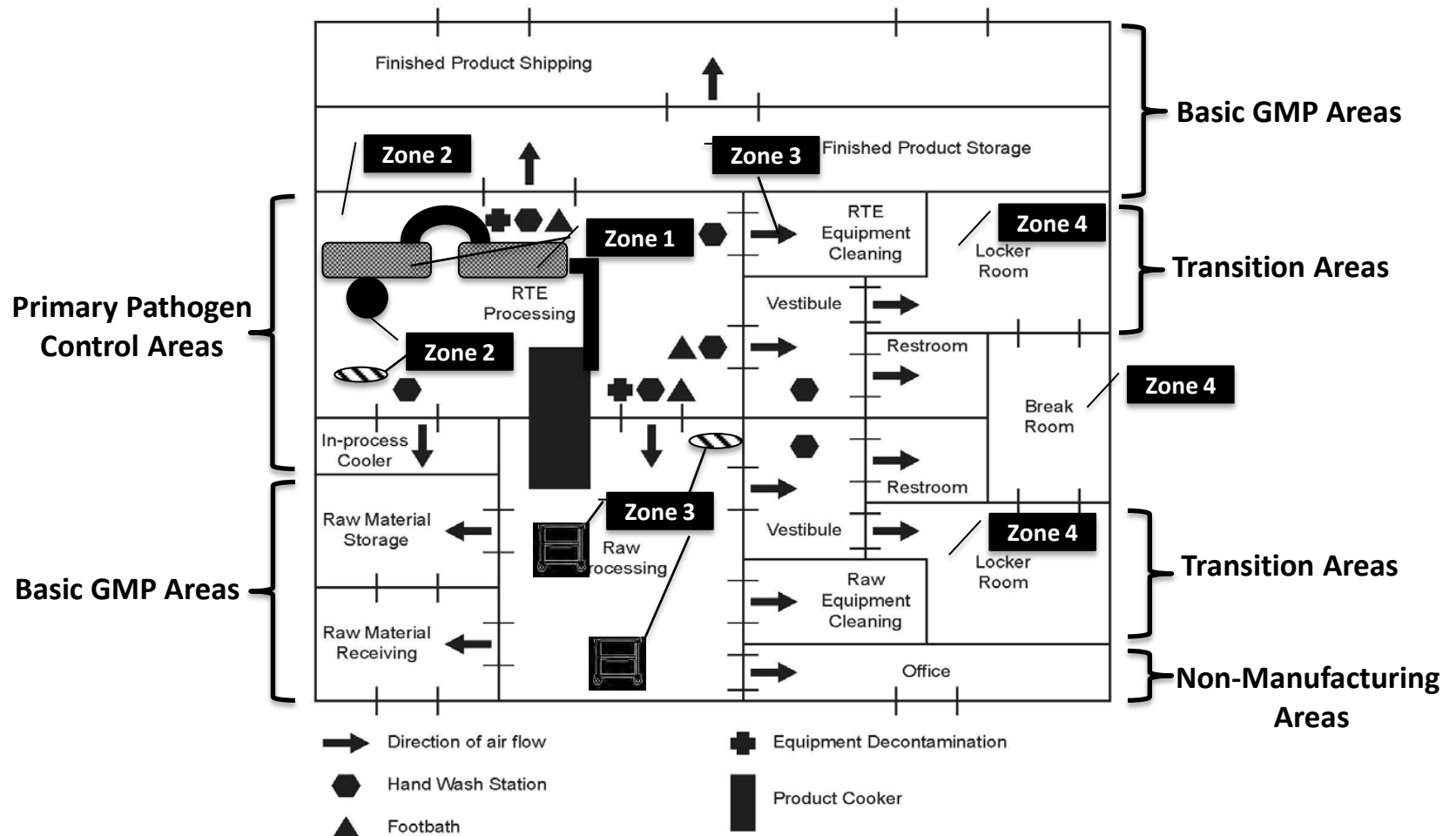


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FACILITY-RELATED HAZARDS CAN BE PREVENTED BY EFFECTIVE SANITATION PREVENTIVE CONTROLS

Perform sampling at locations: determine if hazards are present



Source: Adapted from Food and Drug Administration (2017)

FDA RESOURCES FOR EFFECTIVE SANITATION PREVENTIVE CONTROLS AND THEIR VALIDATION

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 180 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2016-D-2343 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact FDA's Technical Assistance Network by submitting the form available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

August, 2016

Contains Nonbinding Recommendations

Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry

Draft Guidance

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
January 2017



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Food Industry Exposure

Political impact of FSMA

Assumptions are being challenged

The profile of the modern day recall

Risk is more prevalent than we believed



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The most significant risk

FDA enforcement actions

“Swab-a-thon”

PulseNet

Human Illness Standard



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FDA access to records

If FDA believes that there is a reasonable probability that the use of or exposure to [a product] will cause serious adverse health consequences or death ...



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FDA access to records

... then FDA shall have access to the records that are needed to assist FDA in determining whether there is a reasonable probability that the use of or exposure to [a product] will cause serious adverse health consequences or death.



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Conduct that could create liability

Park Doctrine Strict Criminal Liability

Acme, Bidart, Blue Bell, Conagra, Chipotle, Dole

- (1) You are aware of a condition that could lead to someone getting sick;
- (2) you are in a position to correct or eliminate the condition; and
- (3) you fail to correct or eliminate the condition.

Misdemeanor conviction = \$250,000 fine or one year in prison



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Operational Strategies

Effective Sampling

Selective Sampling

Root Cause v. Root Source

Documenting Corrective Actions



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Communication Strategies

1

Avoid using email as a tool to issue criticism

Use email only as a tool to document solutions



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Communication Strategies

2

Assume that everything you write FDA/DOJ will read
Do not press **SEND** unless you are okay with the government reading it*

*If not, (a) do not send; (b) pick up the phone; or (c) involve counsel



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Communication Strategies

3

Always ask yourself,
“What would twelve jurors think?”



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Change the dialogue



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